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SEP 30 2005

PATENT

Attorney Docket No. 101.0053-00000  
Customer No. 22882

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: )  
Gary K. Michelson )  
Serial No.: 08/480,908 ) Group Art Unit: 3764  
Filed: June 7, 1995 ) Examiner: M. Brown  
For: THREADED FRUSTO-CONICAL )  
INTERBODY SPINAL FUSION )  
IMPLANTS )

Mail Stop AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**DECLARATION UNDER 37 C.F.R. § 1.131**

I, Gary K. Michelson, state that I am the sole inventor of the subject matter described and claimed in the above-identified application. Prior to March 27, 1995, I had conceived in this country the subject matter described and claimed in independent claims 1, 25, 69, 108, and 144 of the above-identified application.

Attached hereto as Exhibit A is a drawing showing an embodiment of an implant which I conceived prior to March 27, 1995. The drawing in Exhibit A discloses an implant including the subject matter claimed in pending independent claim 1, which is directed to an implant having a body and a thread with an outer locus "forming a substantially frusto-conical configuration."

In the past, I used the services of Del Blenn of Blenn Air, Inc., a machinist to make at my direction and specification implants embodying my invention. A redacted Declaration with a sketch and a photograph bearing the signature of Del Blenn is attached hereto as Exhibit B. As evidenced by the Declaration of Del Blenn, I had the implant shown in the attached sketch and photograph manufactured according to my direction and specification. The Implant shown in the sketch and photograph of Exhibit B was manufactured prior to March 27, 1995.

The photograph and sketch of Exhibit B each discloses an implant including the subject matter claimed in pending independent claim 25 directed to an implant with "a body having a substantially frusto-conical configuration" and a thread having a locus "forming a substantially cylindrical configuration."

The photograph and sketch of Exhibit B each discloses an implant including the subject matter claimed in pending independent claim 69 directed to an implant with "a body having a substantially frusto-conical configuration" and a thread "for engaging said implant to the adjacent vertebral bodies of the spine."

The photograph and sketch of Exhibit B each discloses an implant including the subject matter claimed in pending independent claim 108 directed to an implant with a body having arcuate portions "being in a diverging relationship to one another" and a thread "for engaging said implant to the adjacent vertebral bodies of the spine."

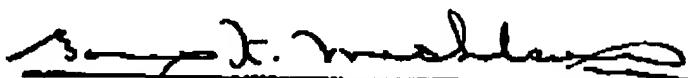
The photograph and sketch of Exhibit B each discloses an implant including the subject matter claimed in pending independent claim 144 directed to an implant with "a body having an outer surface that is substantially continuously tapered from said first end to said second end with external threads defined on said outer surface and extending substantially entirely along said length of said body."

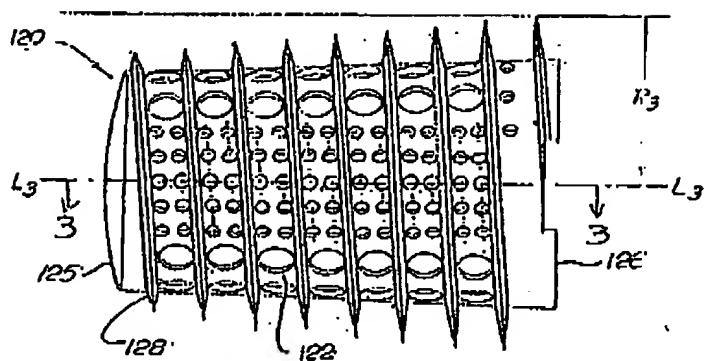
From at least just prior to March 27, 1995 to when the present application was filed on June 7, 1995, my patent attorneys prepared and revised various drafts of the present application according to my instructions. A Declaration of Amadeo F. Ferraro, one of my patent attorneys who prepared, revised, and filed the present application, is submitted concurrently herewith.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

9/30/05

Date

  
Gary Karlin Michelson

**EXHIBIT A**

**EXHIBIT B****BLENN AIR, Inc.****THE FINEST IN PRECISION MACHINING**

229 South Glasgow Avenue, Inglewood, CA 90301 • ( ) 641-1888 • FAX( ) 641-1668

[REDACTED]

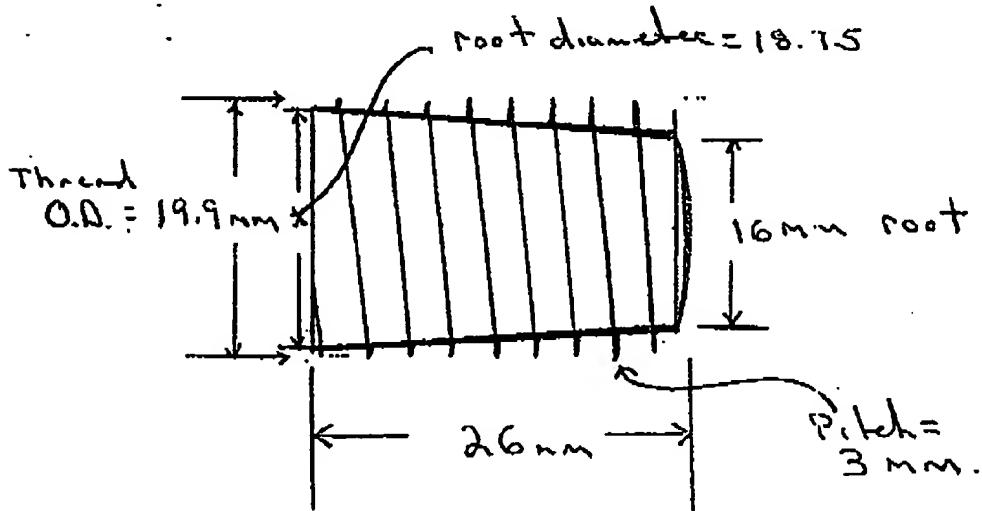
I declare under penalty of perjury that:

On or about the date of [REDACTED] I machined at the direction, and to the specifications of Gary Michelson, M.D., for Karlin Technology Inc., what he described as a screw like medical device.

I have confirmed this date from my own written records.

The device is as shown here and is the device in the photograph labeled, Tapered Threaded Medical Device, which bears my signature; which actual device I personally inspected and confirmed today.

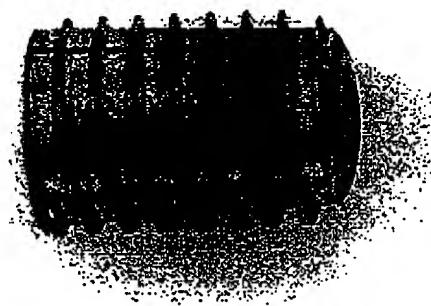
MICHELSON



TAPERED THREADED medical Device

[REDACTED]

TAPERED THREADED Medical Device



See PDL

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P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**DECLARATION OF AMEDEO F. FERRARO**

I, Amedeo F. Ferraro, declare that I am an attorney at law admitted to practice in the State of California and I am registered to practice before the United States Patent and Trademark Office. I have been patent counsel for Dr. Gary Karlin Michelson ("Dr. Michelson") since 1992. The facts set forth in this declaration are based on my own first-hand knowledge. The attached documents have been redacted in order to preserve attorney-client privilege as permitted under MPEP § 715.07, to preserve confidentiality, and to remove material not necessary to establish diligence for the subject matter described and claimed in independent claims 1, 25, 69, 108, and 144 (the "Invention") of the above-identified application.

1. I prepared and filed U.S. Application Serial No. 08/480,908 (hereinafter, the "908 application").
2. During the time period from prior to March 27, 1995 to April 11, 1995, I prepared a draft written description of Dr. Michelson's Invention based on the disclosure provided

to me by Dr. Michelson as evidenced by the document "KARLIN2", a redacted copy of which is attached hereto as Exhibit A.

3. From April 11, 1995 through April 13, 1995, I communicated with Dr. Michelson and prepared a draft patent application for Dr. Michelson's Invention as evidenced by the document "CONICAL.APP," a redacted copy of which is attached hereto as Exhibit B.

4. From April 13, 1995 through April 18, 1995, I communicated with Dr. Michelson and continued to prepare a draft patent application for Dr. Michelson's Invention as evidenced by the document "CONICAL.AP2," a redacted copy of which is attached hereto as Exhibit C.

5. From April 18, 1995 through April 25, 1995, I communicated with Dr. Michelson, communicated with the draftsperson, and continued to prepare a draft patent application for Dr. Michelson's Invention as evidenced by the documents "CONICAL.AP3" and "Fax Coversheet April 20, 1995," a redacted copy of which are attached hereto as Exhibit D.

6. From April 25, 1995 through May 2, 1995, I communicated with Dr. Michelson, communicated with the draftsperson, and continued to prepare a draft patent application for Dr. Michelson's Invention as evidenced by the documents "CONICAL.AP4," "CONICAL.AP5," and "Fax Coversheet April 27, 1995," a redacted copy of which are attached hereto as Exhibit E.

7. From May 2, 1995 through May 17, 1995, I communicated with Dr. Michelson, communicated with the draftsperson, and continued to prepare a draft patent application for Dr. Michelson's Invention as evidenced by the documents "CONICAL.AP6," "CONICAL.AP7," "CONICAL.505," and "Fax Coversheet May 4, 1995," a redacted copy of which are attached hereto as Exhibit F.

8. From May 17, 1995 through June 2, 1995, I communicated with Dr. Michelson, communicated with the draftsperson, and continued to prepare a draft patent application for Dr. Michelson's Invention as evidenced by the documents "Revise 6/2/95," and "Marked-up Drawings," a redacted copy of which are attached hereto as Exhibit G.

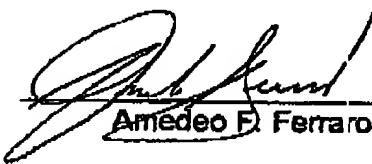
9. From June 2, 1995 through June 7, 1995, I communicated with Dr. Michelson and continued to prepare a draft patent application for Dr. Michelson's Invention as evidenced by the document "fcthrd.ap2" a redacted copy of which is attached hereto as Exhibit H.

10. On June 7, 1995, I communicated with Dr. Michelson and finalized the patent application, and filed the application with the United States Patent and Trademark Office.

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9-30-05

Date



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Amedeo F. Ferraro